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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/018,160 | 11/01/2001 | Ronald Alan Coffee | BER-3.2.050/4167 | 2938 |

26874 7590 08/24/2004
FROST BROWN TODD, LLC
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EXAMINER

OH, SIMON J

| | |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1615

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

45

Office Action Summary

Application No.

10/018,160

Applicant(s)

COFFEE ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-9, 11, 13-16, 18-26, 28-32 and 34-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 4-9, 11, 13-16, 18-26, 28-32 and 34-60 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's petition for extension of time, request for continued examination, amendment, response, and submission of small entity assertion, all received on 29 July 2004.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 12, 27, and 33 under 35 U.S.C. 103(a) as being unpatentable over Coffee in view of Sturzenegger *et al.* and Roche *et al.* is rendered moot with the cancellation of those claims.

The rejection of Claims 4-9, 11, 13-16, 18-26, 28-32, and 34-48 under 35 U.S.C. 103(a) as being unpatentable over Coffee in view of Sturzenegger *et al.* and Roche *et al.* is maintained.

Claims 49-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee in view of Sturzenegger *et al.* and Roche *et al.* is maintained.

The Coffee document discloses processes and apparatuses for forming material by electrohydrodynamic comminution (See Abstract; and Page 4, Lines 1-4). In one aspect, the processes and apparatuses disclosed within the document is capable of producing

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various solid and partially solid forms, such as fibers, fiber segments, fibrils, droplets, particles, webs, and mats. This formed matter may also contain a biologically active ingredient (See Page 2, Line 12 to Page 3, Line 15). Fibers, fiber fragments, and particles of biological material, such as fibrin or collagen may also be formed using the processes and apparatuses (See Page 6, Lines 13-18). Alternatively, the active ingredient may be provided as a coating or core of the fibers, fibrils, or particles (See Page 5, Lines 7-28). Active ingredients may be supplied onto fibers, fibrils, or droplets in the form of a liquid that is dispensed through an outlet nozzle (See Page 22, Lines 23-33). The reference discloses that fibers have been successfully spun with polyhydroxybutyric acid, a resorbable polymer, and with polyvinyl alcohol, a water-soluble polymer (See Page 19, Lines 20-23). In the formation of material provided by the methods and apparatuses disclosed in the reference, the supply of the material may be assisted by an air or inert gas flow (See Claim 32; and Page 30, Lines 27-31). When a melt is used as the material to be formed by the apparatuses and processes disclosed in the reference, the temperature of this material may be controlled by quenching using a cold air or inert gas stream (See Page 11, Lines 17-22).

The Sturzenegger *et al.* patent teaches pharmaceutical dosage forms and methods of making thereof that are created by depositing an active ingredient onto a web, which is then unitized by cutting into individual dosage units (See Columns 16-28). The advantage of such a process is that it allows for dosage forms to be manufactured in a continuous process, eliminating the need for batch lot manufacturing (See Column 3 and 4). The web itself is preferably hydrophilic and disintegrable in water or degradable in body fluids (See Column 6, Lines 16-24). In one embodiment, the web is made from a

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polymeric material that generally comprises an organic film-former, a plasticizer, modifiers such as optional ingredients, and fugitive solvents (See Column 7, Lines 19-28). Film-forming materials include proteins such as gelatin (See Column 7, Lines 37-41). Fugitive solvents may be water, or an organic solvent, such as ethyl alcohol, or a combination of such solvents (See Column 8, Lines 54-60).

The Roche *et al.* patent is used here merely as a teaching reference to show that additives such as saccharin and peppermint flavoring are commonly known in the pharmaceutical arts (See Column 8, Lines 31-58).

It would be obvious to one of ordinary skill in the art to combine the disclosures of Coffee, Sturzenegger *et al.*, and Roche *et al.* into the objects of the instantly claimed invention. One of ordinary skill in the art would be motivated to combine the Coffee and Sturzenegger *et al.* references in order to devise a continuous method of manufacturing dosage forms that utilizes a more sophisticated method of producing a mat that is created from fibers containing an active ingredient. As explained above, the Roche *et al.* patent is relied upon merely as a teaching reference. It is the position of the examiner that one of ordinary skill in the art could combine the collective disclosures of the prior art with a reasonable expectation of success. It is also the position of the examiner that the selection of fish gelatin over gelatin of other sources is not critical, absent a demonstration of criticality by the applicant of this particular selection. Claim limitations containing specific amounts of specific ingredients are considered by the examiner to be attainable by one of ordinary skill in the art through routine experimentation, and are not considered to be critical. Claim limitations reciting specific moist tissue surfaces are

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considered by the examiner to be recitations of intended use, and thus do not carry patentable weight.

Thus, the instantly claimed invention is prima facie obvious.

Response to Arguments

Applicant's arguments filed 29 July 2004 have been fully considered but they are not persuasive.

The newly incorporated claim limitations concerning the recitation of specific moist tissue surfaces or the exclusion of specific moist tissue surfaces are not considered by the examiner to carry any patentable weight, as the examiner sees them as recitations of intended use of a product. Such limitations that exist within the apparatus claims are directed to the finished product made by the apparatus; there is no structural modification to the apparatus itself. These same limitations that exist within the claims of methods of manufacturing are directed to the finished product; there is no structural modification to the method steps themselves.

New claim limitations directed to at least partially coating the active ingredient within the claimed fiber web or mat are considered by the examiner to be so broad that the examiner does not see a patentable distinction between the instant claims and what has been disclosed by the Coffee reference. The examiner shifts the burden onto the applicant to show what sort of patentably distinct property this would impart to the instantly claimed product.

Furthermore, the examiner disagrees with the applicant's assessment of the Sturzenegger *et al.* reference. The disclosed product is described very simply as a web,

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and in the views of the examiner, holes and voids will be inherent in such a product. It is the position of the examiner that one of ordinary skill would not reasonably view such an inherent property as a defect or as property to be avoided. As such, the examiner maintains the previous position that it would be obvious for one of ordinary skill in the art to combine the two references, along with the Roche *et al.* reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1615

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